#### 103D CONGRESS 1ST SESSION

# H. R. 1627

To amend the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act, and for other purposes.

### IN THE HOUSE OF REPRESENTATIVES

APRIL 1, 1993

Mr. Lehman (for himself, Mr. Bliley, Mr. Rowland, Mr. Smith of Oregon, Mr. Roberts, Mr. Penny, Mr. English of Oklahoma, Mr. Holden, Mr. Emerson, Mr. Kingston, Mr. Sarpalius, Mr. Ewing, Mr. Dooley, Mr. Johnson of South Dakota, Mr. Barrett of Nebraska, Mr. Boehner, Mr. Combest, Mr. Doolittle, Mr. Condit, Mr. Bishop, Mr. Gunderson, Mr. Pomeroy, Mr. Allard, Mr. Towns, Mr. Cooper, Mr. Hall of Texas, Mr. McMillan, Mr. Hastert, Mr. Upton, Mr. Paxon, Mr. Klug, Mr. Franks of Connecticut, Mr. Manton, Mr. Boucher, Mr. Crapo, Mr. Barton of Texas, Mr. Gillmor, Mr. Oxley, Mr. Tauzin, and Mr. Moorehead) introduced the following bill; which was referred jointly to the Committees on Agriculture and Energy and Commerce

#### August 18, 1993

Additional sponsors: Mr. Johnson of Georgia, Mr. Parker, Mr. Darden, Mr. Lipinski, Mr. Stump, Mr. Hancock, Mr. Bereuter, Mr. Walsh, Mr. Dornan, Mr. Bateman, Mr. Hughes, Mr. Smith of Michigan, Mr. HERGER, Mr. BAKER of Louisiana, Mr. PAYNE of Virginia, Mr. INHOFE, Mr. Coble, Mr. Sundquist, Mr. Ravenel, Mr. Pombo, Mr. Sisisky, Mr. Wise, Mr. LaRocco, Mr. Camp, Mr. Canady, Mr. Walker, Mr. ROTH, Mr. HOUGHTON, Mr. COLEMAN, Mr. STEARNS, Mr. THOMAS of Wyoming, Mr. Hefner, Mr. McCrery, Ms. Danner, Mr. Goodling, Mr. McDade. Mr. Valentine. Mr. Burton of Indiana. Mr. Dreier. Mr. Lewis of Florida, Mr. Clyburn, Mr. Gekas, Mr. Deal, Mr. Kan-JORSKI, Mr. GINGRICH, Mr. SHUSTER, Mr. GRAMS, Mr. TAYLOR of North Carolina, Mr. Traficant, Mr. Schaefer, Mr. Gallegly, Mr. Hutch-INSON, Mr. Andrews of New Jersey, Mr. Peterson of Minnesota, Ms. Dunn, Mr. Gallo, Mr. Ballenger, Mr. Zeliff, Mr. Goodlatte, Mr. BAKER of California, Mr. Armey, Mr. Brewster, Mr. Peterson of Florida, Mr. HANSEN, Mrs. LLOYD, Mr. SOLOMON, Mr. NEAL of North Carolina, Mr. Bonilla, Mr. Gonzalez, Mr. Gutierrez, Mr. Collins

of Georgia, Mr. Duncan, Mr. Cox, Mr. Lightfoot, Ms. Kaptur, Mr. Young of Alaska, Mr. Gilchrest, and Mr. Fazio

A BILL

- To amend the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act, and for other purposes.
  - 1 Be it enacted by the Senate and House of Representa-
  - 2 tives of the United States of America in Congress assembled,
  - 3 SECTION 1. SHORT TITLE.
  - 4 This Act may be cited as the "Food Quality Protec-
  - 5 tion Act of 1993".
  - 6 TITLE I—CANCELLATION AND
  - 7 **SUSPENSION**
  - 8 SEC. 101. REFERENCE.
  - 9 Whenever in this title an amendment or repeal is ex-
- 10 pressed in terms of an amendment to, or repeal of, a sec-
- 11 tion or other provision, the reference shall be considered
- 12 to be made to a section or other provision of the Federal
- 13 Insecticide, Fungicide, and Rodenticide Act.
- 14 SEC. 102. CANCELLATION.
- 15 Section 6(b) (7 U.S.C. 136d(b)) is amended to read
- 16 as follows:

1 "(b) CANCELLATION AND CHANGE IN CLASSIFICA-2 TION OR OTHER TERMS OR CONDITIONS OF REGISTRA-3 TION.—

"(1) AUTHORITY.—Notwithstanding any other provision of this Act, the Administrator may, by use of informal rulemaking under this subsection, prescribe requirements regarding the composition, packaging, and labeling of a pesticide (or a group of pesticides containing a common active or inert ingredient), or may classify any such pesticide, or may prohibit the registration or continued registration of any such pesticide for some or all purposes, to the extent necessary to assure that the pesticide, when used in accordance with widespread and commonly recognized practice, does not generally cause unreasonable adverse effects on the environment.

## "(2) Basis for rule.—

"(A) The Administrator may not initiate a rulemaking under this subsection unless the rulemaking is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse effects to man or to the environment.

"(B)(i) The Administrator shall submit to a scientific peer review committee established

by the Administrator the validated test or other significant evidence upon which the Administrator proposes to base a rulemaking under paragraph (1).

- "(ii) The scientific peer review committee shall provide written recommendations to the Administrator as to whether the test or evidence reviewed satisfies the criteria under paragraph (1) for initiating a rulemaking under paragraph (1).
- "(iii) The scientific peer review committee shall consist of employees of or consultants to the Environmental Protection Agency who have not been involved in any previous analysis of the validated test or significant evidence presented to the committee and who are expert in the physical or biological disciplines involved in the proposed rulemaking.

# "(3) Prenotice procedures.—

"(A) The Administrator may not initiate a rulemaking under paragraph (1) until the Administrator has furnished to the registrant of each affected pesticide a notice that includes a summary of the validated test or other significant evidence upon which the Administrator

proposes to base the rulemaking and the basis for a determination that such test or evidence raises prudent concerns that the pesticide causes unreasonable adverse risks to man or to the environment. A registrant shall have 30 days after receipt of a notice provided under this subparagraph to respond to such notice.

"(B) At the same time that the Administrator furnishes notice to registrants of the pesticide under subparagraph (A), the Administrator shall also furnish such notice to the Secretary of Agriculture and the Secretary of Health and Human Services. Upon receipt of such notification, the Secretary of Agriculture, when an agricultural commodity is affected, shall prepare an analysis of the benefit and use data of the pesticide and provide the analysis to the Administrator.

# "(4) ADVANCE NOTICE TO PUBLIC.—

"(A) The Administrator after receiving the recommendation of the peer review committee established under paragraph (2)(B) together with any comments submitted by the Secretary of Agriculture, the Secretary of Health and

1	Human Services, and any registrant shall ei-
2	ther—
3	"(i) issue an advance notice of pro-
4	posed rulemaking, or
5	"(ii) issue a notice of a proposed deci-
6	sion not to initiate a rulemaking under
7	paragraph (1).
8	"(B) The Administrator shall publish such
9	notice in the Federal Register and provide a pe-
10	riod of not less than 60 days for comment
11	thereon. The notice shall contain a statement of
12	its basis and purpose, which shall include a
13	summary of—
14	"(i) the factual data on which the no-
15	tice is based,
16	"(ii) the major scientific assumptions
17	underlying the notice, and
18	"(iii) a summary of the notice under
19	paragraph (3) and any significant com-
20	ments received from any registrant, the
21	Secretary of Agriculture, and the Secretary
22	of Health and Human Services.
23	"(C) If the Administrator, after consider-
24	ing any comments received, decides not to issue
25	a notice of proposed rulemaking, the Adminis-

trator shall publish in the Federal Register a
notice setting forth the decision and its basis.

"(5) DOCKET.—For each rulemaking under
paragraph (1), the Administrator shall establish a

docket. The docket shall include a copy of the notice under paragraph (3), of any notice issued under paragraph (4), of the notice of proposed rulemaking under paragraph (6), of each timely comment filed with the Administrator, of the report of the Scientific Advisory Panel under paragraph (8), of a record of each hearing held by the Administrator in connection with the rulemaking, and of the final rule or decision to withdraw the rule. Information in the docket shall be made available to the public consistent with the requirements of section 10. No factual material that has not been entered into the docket in a timely manner may be relied upon by the Administrator in issuing a final rule or in withdrawing a proposed rule or by any person in a judicial review proceeding, except for—

- "(A) information of which the Administrator may properly take official notice, or
- "(B) information of which a court may properly take judicial notice.
- 25 "(6) Notice of proposed rulemaking.—

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1	"(A) Not less than 60 days after an ad-
2	vance notice of proposed rulemaking, except as
3	provided in paragraph (14), the Administrator
4	may issue a notice of proposed rulemaking. The
5	notice of proposed rulemaking shall include a
6	statement of its basis and purpose, a request
7	for any additional data needed, and a bibliog-
8	raphy of all significant scientific data and stud-
9	ies on which the proposed rule is based. The
10	statement of basis and purpose shall include a
11	summary of—
12	"(i) the factual data on which the pro-
13	posed rule is based,
14	"(ii) the major scientific assumptions
15	legal interpretations, and policy consider-
16	ations underlying the proposed rule,
17	"(iii) a summary of available risk-ben-
18	efit information, including benefits and use
19	information as provided by the Secretary
20	of Agriculture, and
21	"(iv) the Administrator's analysis and
22	tentative conclusions regarding the bal-
23	ancing of such risks and benefits.
24	"(B) Registrants of the pesticide and any
25	person who submits comments on the proposed

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rule shall make a report to the Administrator of all scientific data and studies in such person's possession concerning the risks and benefits of the pesticide that are the subject of the rulemaking and were not included in the bibliography included in the notice required in subparagraph (A). If such person receives additional scientific data or studies pertinent to the rulemaking that were not included in such bibliography, the person shall make a report of such scientific data and studies to the Administrator promptly after receipt. If the Administrator receives reports containing additional data concerning risks or benefits, the Administrator shall revise the bibliography to reflect such data and make the revised bibliography available to the public.

"(C) The Administrator shall provide a comment period of not less than 90 days after the publication of the notice of proposed rule-making. During such period any person may submit comments, data, or documentary information on the proposed rule. Promptly upon receipt by the Administrator, all written comments and documentary information on the pro-

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posed rule received from any person for inclusion in the docket during the comment period, shall be placed in the docket.

"(D) At the same time that the Administrator publishes notice under subparagraph (A), the Administrator shall provide the Secretary of Agriculture and the Secretary of Health and Human Services with a copy of the proposed rule. Not later than 90 days after the publication of the notice of proposed rulemaking, the Secretary of Agriculture and the Secretary of Health and Human Services may provide comments on such proposed rule. When an agricultural commodity is affected, the Secretary of Agriculture shall provide to the Administrator an analysis of the impact of the proposed action on the domestic and global availability and prices of agricultural commodities and retail food prices and any associated societal impacts (including consumer nutrition and health and low-income consumers).

# "(7) Informal Hearing.—

"(A) Any person who has submitted a comment may, not later than 15 days after the close of the comment period, request of the Ad-

ministrator an informal hearing on questions of fact pertaining to the proposed rule or comments thereon. Upon such request, the Administrator shall schedule an informal hearing not to exceed 20 days duration, and to conduct not later than 60 days after the close of the comment period. The Administrator shall announce the time, place, and purpose of the hearing in the Federal Register. The informal hearing shall be limited to addressing questions of fact raised by materials in the docket. A transcript shall be made of any oral presentation, discussion, or debate and included in the docket.

"(B) The Administrator shall appoint a presiding officer who shall have the authority to administer oaths, regulate the course of the hearing, conduct prehearing conferences, schedule presentations, and exclude irrelevant, immaterial, or unduly repetitious evidence.

"(C) The presiding officer shall conduct the informal hearing in a manner that encourages discussion and debate on questions of fact regarding the docket. The Administrator shall designate one or more employees of the Environmental Protection Agency to participate in

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the hearing. Any person who submitted a comment on the proposed rule may participate in the hearing and shall be entitled to present evidence and argument to support the participant's position or rebut a contrary position and may choose to present materials in oral or written form.

"(8) REVIEW BY **SCIENTIFIC** ADVISORY PANEL.—At the time the Administrator issues a notice of proposed rulemaking under paragraph (6), the Administrator shall provide a copy of such notice to the Scientific Advisory Panel established under section 25(d). If any person submits comments under paragraph (6) in opposition to the proposed rule, the Administrator shall request the comments, evaluations, and recommendations of the Panel as to the impact on health and the environment of the proposed rule and on any disputed issues of fact or scientific policy that appear to be of significance in the rulemaking. The Panel may hold a public hearing to discuss the proposed rule. The Panel shall provide a report to the Administrator not later than 30 days after the close of comment period (or, if a hearing has been requested under paragraph (7), not later than 30 days after the end of such hearing).

The Administrator shall allow a reasonable time for written public comment on the Panel's report. A copy of the Panel's report and any comments shall be included in the rulemaking docket.

"(9) Final action.—After considering all material in the docket, the Administrator shall publish in the Federal Register either a final rule or a withdrawal of the proposed rule. The Administrator may not prohibit a use of a pesticide if alternative requirements will assure that the pesticide, when used in accordance with widespread and commonly recognized practice, will not generally cause unreasonable adverse effects on the environment. In taking any final action, the Administrator shall take into account the impact of the action on production and prices of agricultural commodities, retail food prices, and otherwise on agricultural economy. The final rule or withdrawal of the proposal shall be accompanied by a statement that—

- "(A) explains the reasons for the action;
- "(B) responds to any comments made by the Secretary of Agriculture or the Secretary of Health and Human Services, and responds to any report of the Scientific Advisory Panel;

1	"(C) responds to each significant comment
2	contained in the docket; and
3	"(D) in the case of a final rule—
4	"(i) explains the reasons for any
5	major differences between the final rule
6	and the proposed rule;
7	"(ii) describes the impact of the final
8	rule on production and prices of agricul-
9	tural commodities, retail food prices, and
10	otherwise on the agricultural economy; and
11	''(iii) explains any significant dis-
12	agreements the Administrator may have
13	with the comments, evaluations, or rec-
14	ommendations contained in the report
15	under paragraph (8) or the benefits and
16	use information described in paragraph
17	(6)(A)(iii) and analysis in paragraph
18	(6)(D) as it bears on the final rule.
19	A final rule issued under this subsection shall be ef-
20	fective upon the date of its publication in the Fed-
21	eral Register.
22	"(10) Modification or cancellation.—
23	"(A) A final rule shall state any require-
24	ments, classifications, or prohibitions imposed
25	by the rule, and shall state that each affected

registrant shall have a 30-day period from the date of publication of the rule in the Federal Register to apply for an amendment to the registration to comply with the rule or to request voluntary cancellation of the registration. However, if the rule unconditionally prohibits all uses of a pesticide, the rule may provide that cancellation of the registration of the pesticide is effective upon publication of the rule. The final rule may prohibit or limit distribution or sale by the registrant of the affected pesticide to any other person in any State during such 30-day period.

"(B) Notwithstanding any other provision of this Act, if an application for an amendment to the registration to make it comply with a rule issued under subparagraph (A) is not submitted within such 30-day period, the Administrator may issue and publish in the Federal Register an order canceling the registration, effective upon the date of publication of the order in the Federal Register.

"(11) DENIAL OF APPLICATIONS.—Notwithstanding any other provision of this Act, no application for initial or amended registration of any pes-

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ticide under section 3 or 24(c) may be approved if the registration would be inconsistent with a rule in effect under this subsection.

"(12) AMENDMENT OF RULE.—A registrant, or other interested person with the concurrence of the registrant, may petition for the amendment or revocation of a rule that has been issued under this subsection. The petition shall state the factual material and argument that form the basis for the petition. The Administrator shall publish a notice of the petition in the Federal Register and allow a 60-day comment period thereon. Not later than 180 days after publication of the notice, the Administrator shall determine whether to deny the petition or to propose to amend or revoke the rule, and publish the determination and its basis in the Federal Register. In making such a determination, the Administrator shall give due regard to the desirability of finality, to the opportunity that the petitioner had to present the factual material and argument in question in the prior rulemaking proceeding, and to any new evidence submitted by the petitioner. If the Administrator proposes to amend or revoke the rule, then the procedures established by paragraph (1) and paragraphs (6) through (9) apply. A denial of a peti-

- tion shall be judicially reviewable as provided in paragraph (13).
- "(13) JUDICIAL REVIEW.—A decision not to initiate a rulemaking published under paragraph (4), a final rule or a withdrawal of a proposed rule published under paragraph (9) or a denial of a petition under paragraph (12) shall be judicially reviewable in the manner specified by section 16(b)(2).
- 9 "(14) EXCEPTION TO REQUIREMENTS.—If the 10 Administrator finds it necessary to issue a suspen-11 sion order under subsection (c), the Administrator 12 may waive the requirements of paragraphs (3) and 13 (4) of this subsection.".

#### 14 SEC. 103. PESTICIDES IN REVIEW.

- 15 If the Administrator, on or before January 1, 1993,
- 16 has published a document instituting a special review pro-
- 17 ceeding or public interim administrative review proceeding
- 18 with respect to a particular pesticide or active ingredient
- 19 thereof, the Administrator may, in lieu of proceeding
- 20 under section 6(b) of the Federal Insecticide, Fungicide,
- 21 and Rodenticide Act as amended by the Food Quality Pro-
- 22 tection Act of 1993, elect to continue such review proceed-
- 23 ing and, upon its completion, take action as warranted in
- 24 accordance with sections 3(c)(6), 6(b), and 6(d) as those

- 1 sections were in effect on the day before the date of enact-
- 2 ment of the Food Quality Protection Act of 1993.
- 3 SEC. 104. SUSPENSION.
- 4 (a) Section 6(c)(1).—The second sentence of sec-
- 5 tion 6(c)(1) (7 U.S.C. 136d(c)(1)) is revised to read: "Ex-
- 6 cept as provided in paragraph (3), no order of suspension
- 7 may be issued under this subsection unless the Adminis-
- 8 trator has issued, or at the same time issues, a proposed
- 9 rule under subsection (b).".
- 10 (b) Section 6(c)(3).—Section 6(c)(3) (7 U.S.C.
- 11 136d(c)(1)) is amended by inserting after the first sen-
- 12 tence the following new sentence: "The Administrator may
- 13 issue an emergency order under this paragraph before is-
- 14 suing a proposed rule under subsection (b), provided that
- 15 the Administrator shall proceed expeditiously to issue a
- 16 proposed rule.".
- 17 SEC. 105. TOLERANCE REEVALUATION AS PART OF
- 18 **REREGISTRATION**.
- 19 Section 4(g) (7 U.S.C. 136b(g)) is amended in para-
- 20 graph (2) by adding at the end the following:
- 21 "(E) As soon as the Administrator has
- sufficient information with respect to the die-
- tary risk of a particular active ingredient, but
- in any event no later than the time the Admin-
- 25 istrator makes a determination under subpara-

1	graph (C) or (D) with respect to pesticides con-
2	taining a particular active ingredient, the Ad-
3	ministrator shall—
4	"(i) reassess each associated tolerance
5	and exemption from the requirement for a
6	tolerance issued under section 408 of the
7	Federal Food, Drug, and Cosmetic Act (21
8	U.S.C. 346a),
9	"(ii) determine whether such tolerance
10	or exemption meets the requirements of
11	that Act,
12	"(iii) determine whether additional
13	tolerances or exemptions should be issued
14	''(iv) publish in the Federal Register a
15	notice setting forth the determinations
16	made under this subparagraph, and
17	"(v) commence promptly such pro-
18	ceedings under this Act and section 408 of
19	the Federal Food, Drug, and Cosmetic Act
20	as are warranted by such determinations."
21	SEC. 106. SCIENTIFIC ADVISORY PANEL.
22	The first sentence of section 25(d) (7 U.S.C
23	136w(d)) is amended by striking out "The Administrator
24	shall" and inserting in lieu thereof "(1) IN GENERAL.—

The Administrator shall" and such section is amended by adding at the end the following: 3 "(2) Science review board.—There is established a Science Review Board to consist of 60 sci-5 entists who shall be available to the Scientific Advisory Panel to assist in reviews conducted by the 6 7 Panel. The Scientific Advisory Panel shall select the scientists from 60 nominations submitted each by 8 the National Science Foundation and the National 9 10 Institutes of Health. Members of the Board shall be 11 compensated in the same manner as members of the Panel.". 12 SEC. 107. CONFORMING AMENDMENTS. (a) Section 3(c)(6).—Section 3(c)(6) (7 U.S.C. 14 15 136a(c)(6)) is amended to read as follows: 16 "(6) Denial of application for registra-17 TION.— 18 "(A) Except as provided in subparagraph 19 (B), if the Administrator proposes to deny an 20 application for registration because it does not satisfy the requirements of paragraph (5), the 21 22 Administrator shall notify the applicant of the proposal and the reasons (including the factual 23 24 basis thereof). Unless the applicant makes the

necessary corrections to the application and no-

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tifies the Administrator thereof during the 30day period beginning with the day after the date the applicant receives the notice, or during that time the applicant submits a request for a hearing, the Administrator may issue an order denying the application. If during that time the Administrator does not receive such corrections to the application or such a request for hearing, the Administrator may issue an order denying the application. Such an order shall be published in the Federal Register and shall not be subject to judicial review. If during that time the Administrator receives a request for a hearing, a hearing shall be conducted under section 6(d) of the Act. If such a hearing is held, a decision after completion of such hearing shall be final and shall be subject to judicial review under section 16(b)(1) of this Act.

"(B) The Administrator may deny an application for registration because it does not comply with the requirements of a rule issued under section 6(b) of this Act. The Administrator shall notify the applicant of such denial. Such notice shall explain why the application does not comply with such requirements and

shall state that the applicant may petition to 1 2 amend or revoke such rule under section 3 6(b)(12) of this Act.". (b) Section 3(c)(8).—Section 3(c)(8) (7 U.S.C. 4 136a(c)(8)) is repealed. 5 (c) Section 3(d).—Section 3(d) (7 U.S.C. 136a(dd)) 6 is amended— (1) in paragraph (1)(A), by striking out "on the 8 initial classification and registered pesticides" and 9 inserting in lieu thereof "under section 6(b) of this 10 Act. Registered pesticides"; and 11 (2) in paragraph (2), by striking out all that 12 follows "on the environment," and inserting in lieu 13 thereof "the Administrator may initiate a proceeding 14 15 under section 6(b) of the Act.". (d) Section 4(e).—Section 4(e)(3)(B)(iii)(III) (7 16 U.S.C. 136b(e)(3)(B)(iii)(III)) is amended— 18 (1) by striking out "section 6(d), except that 19 the" and inserting in lieu thereof "section 6(d). 20 The"; and (2) by inserting after "guidelines." the follow-21 22 ing: "If a hearing is held, a decision after completion 23 of such hearing shall be final.";

- 1 (e) SECTION 6(c).—Section 6(c) (7 U.S.C. 136d(c))
  2 is amended in paragraph (4) by striking out "section 16"
  3 and inserting in lieu thereof "section 16(b)(1)".
  4 (f) SECTION 6(d).—Section 6(d) (7 U.S.C. 136d(d))
- 4 (f) Section 6(d).—Section 6(d) (7 U.S.C. 136d(d))

  5 is amended—
  - (1) by revising the first sentence to read as follows: "If a hearing is requested pursuant to section 3(c)(2)(B)(iv), 3(c)(6), 4(e)(3)(B)(iii)(III), 6(c)(2), or 6(e)(2), such hearing shall be held for the purpose of receiving evidence relevant and material to the issues raised by the request for hearing."; and
    - (2) by striking all that follows the eighth sentence and inserting the following: "A hearing under this subsection shall be held in accordance with the provisions of sections 554, 556, and 557 of title 5, United States Code. As soon as practicable after the completion of the hearing, the Administration shall issue a final order setting forth the Administrator's decision. Such order and decision shall be based only on substantial evidence of record of such hearing, shall set forth detailed findings of fact upon which the order is based, and shall be subject to judicial review under section 16(b)(1)."

Section 16(a).—Section 16(a) (7 U.S.C. 1 136n(a)) is amended by inserting "or a proceeding under section 6(b)" after "a hearing". (h) SECTION 16(b).—Section 16(b) (17 U.S.C. 4 136n(b)) is amended— (1) by striking out "(b) REVIEW BY COURT OF 6 APPEALS.—In the case of" and inserting in lieu 7 8 thereof the following: 9 "(b) REVIEW BY COURT OF APPEALS.— 10 "(1) Review of Certain Orders.—In the case of": 11 (2) by striking "under this section" in the sixth 12 sentence of paragraph (1) (as so designated) and in-13 serting "under this paragraph"; and 14 15 (3) by adding at the end the following new 16 paragraph: 17 "(2) REVIEW OF CERTAIN RULES.—In the case 18 of actual controversy as to the validity of any rule 19 issued by the Administrator under section 6(b)(9), 20 any decision by the Administrator under section 21 6(b)(4) or 6(b)(9) not to issue a proposed rule or to 22 withdraw a proposed rule, or any denial of a petition 23 to revoke or amend a final rule under section

6(b)(12), any person who will be adversely affected

by such rule or decision and who has filed comments

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in the proceeding leading to the rule or decision may obtain judicial review by filing a petition in the United States court of appeals for the circuit wherein such person resides or has a place of business, within 60 days after the entry of such order. A copy of the petition shall be forthwith transmitted to the Administrator or any officer designated by the Administrator for that purpose, and thereupon the Administrator shall file in court the record of the proceedings on which the Administrator based such rule or decision, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition the court shall have exclusive jurisdiction to affirm or set aside such rule or decision in whole or in part. The standard review shall be that set forth in section 706 of title 5, United States Code. The judgment of the court under this paragraph shall be final, subject to review by the Supreme Court upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order.".

- 1 (i) Section 25(a).—Section 25(a) (7 U.S.C.
- 2 136w(a)) is amended by adding a new paragraph (5) at
- 3 the end, to read as follows:
- 4 "(5) Exception.—The requirements of this
- 5 subsection shall not apply to any rule or rulemaking
- 6 proceeding under section 6(b).".
- 7 (j) Section 25(d).—Section 25(d) (7 U.S.C.
- 8 136w(d)) is amended—
- 9 (1) in the first sentence by striking out "in no-
- tices of intent issued under subsection 6(b) and";
- 11 and
- 12 (2) in the second sentence by striking out "no-
- tices of intent and" and by striking out "section
- 14 6(b) or".
- 15 (k) Section 25(e).—Section 25(e) (7 U.S.C.
- 16 136w(e)) is amended by striking out the period at the end
- 17 of the second sentence and substituting ", except for any
- 18 action that may be taken under section 6(b).".

## 19 TITLE II—DATA COLLECTION

- 20 SEC. 201. COLLECTION OF PESTICIDE USE INFORMATION.
- 21 The Secretary of Agriculture shall collect data of
- 22 Statewide or regional significance on the use of pesticides
- 23 to control pests and diseases of major crops and crops of
- 24 dietary significance, including fruits and vegetables. Such
- 25 data shall be collected by surveys of farmers or from other

- 1 sources offering statistically reliable data. The Secretary
- 2 shall, as appropriate, coordinate with the Administrator
- 3 of the Environmental Protection Agency in the design of
- 4 such surveys and make available to the Administrator the
- 5 aggregate results of such surveys to assist the Adminis-
- 6 trator in developing exposure calculations and benefits de-
- 7 terminations with respect to pesticide regulatory decisions.
- 8 SEC. 202. INTEGRATED PEST MANAGEMENT.
- 9 Section 28(c) of the Federal Insecticide, Fungicide,
- 10 and Rodenticide Act (7 U.S.C. 136w-3(c)) is amended—
- 11 (1) by designating the text of such section as
- paragraph (1) with the margin indented one em, and
- 13 (2) by adding at the end the following:
- 14 "(2) The Administrator and the Secretary of Agri-
- 15 culture shall research, develop, and disseminate integrated
- 16 pest management techniques and other pest control meth-
- 17 ods that enable producers to reduce or eliminate applica-
- 18 tions of pesticides which pose a greater than negligible die-
- 19 tary risk to humans, with a special focus on crops critical
- 20 to a balanced, healthy diet and which are considered as
- 21 minor crops in terms of acreage produced.".

1	TITLE III—AMENDMENTS TO THE FED-
2	ERAL FOOD, DRUG, AND COSMETIC
3	ACT
4	SEC. 301. REFERENCE.
5	Whenever in this title an amendment is expressed in
6	terms of an amendment to a section or other provision,
7	or refers to a section or other provision, the reference shall
8	be considered to be made to a section or other provision
9	of the Federal Food, Drug, and Cosmetic Act.
10	SEC. 302. DEFINITIONS.
11	(a) Section 201(q) (21 U.S.C. $321(q)$ ) is amended to
12	read as follows:
13	``(q)(1) The term 'pesticide chemical' means—
14	"(A) any substance that is a pesticide within
15	the meaning of the Federal Insecticide, Fungicide,
16	and Rodenticide Act, or
17	"(B) any active or inert ingredient of a pes-
18	ticide within the meaning of the Federal Insecticide,
19	Fungicide, and Rodenticide Act.
20	"(2) The term 'pesticide chemical residue' means a
21	residue in or on raw agricultural commodity or processed
22	food of—
23	"(A) a pesticide chemical, or
24	"(B) any other added substance that is present
25	in the commodity or food primarily as a result of the

- 1 metabolism or other degradation of a pesticide
- 2 chemical.
- 3 "(3) Notwithstanding paragraphs (1) and (2), the
- 4 Administrator may by regulation except a substance from
- 5 the definition of 'pesticide chemical' or 'pesticide chemical
- 6 residue' if—
- 7 "(A) its occurrence as a residue on a raw agri-
- 8 cultural commodity or processed food is attributable
- 9 primarily to natural causes or to human activities
- not involving the use of any substances for a pes-
- ticidal purpose in the production, storage, process-
- ing, or transportation of any raw agricultural com-
- modity or processed food, and
- 14 "(B) the Administrator, after consultation with
- the Secretary, determines that the substance more
- appropriately should be regulated under one or more
- provisions of this Act other than sections
- 18 402(a)(2)(B) and 408.".
- 19 (b) Paragraphs (1) and (2) of section 201(s) (21
- 20 U.S.C. 321(s)) are amended to read as follows:
- 21 "(1) a pesticide chemical residue in or on a raw
- agricultural commodity or processed food; or
- 23 "(2) a pesticide chemical; or".
- 24 (c) Section 201 (21 U.S.C. 321) is amended by add-
- 25 ing at the end the following:

- 1 "(bb) The term 'processed food' means any food
- 2 other than a raw agricultural commodity and includes any
- 3 raw agricultural commodity that has been subject to proc-
- 4 essing, such as canning, cooking, freezing, dehydration, or
- 5 milling.
- 6 "(cc) The term 'Administrator' means the Adminis-
- 7 trator of the United States Environmental Protection
- 8 Agency.".
- 9 SEC. 303. PROHIBITED ACTS.
- 10 Section 301(j) (21 U.S.C. 331(j)) is amended—
- 11 (1) by striking the period at the end; and
- 12 (2) by adding at the end ", or the violation of
- section 408(g)(2) or any regulation issued under
- that section.".
- 15 SEC. 304. ADULTERATED FOOD.
- 16 Section 402(a)(2) (21 U.S.C. 342(a)(2)) is amended
- 17 to read as follows:
- 18 "(2)(A) if it bears or contains any added poi-
- sonous or added deleterious substance (other than a
- substance that is a pesticide chemical residue in or
- on a raw agricultural commodity or processed food,
- a food additive, a color additive, or a new animal
- drug) that is unsafe within the meaning of section
- 24 406:

1	$\mbox{``(B)}$ if it bears or contains a pesticide chemical
2	residue that is unsafe within the meaning of section
3	408(a); or
4	"(C) if it is or if it bears or contains—
5	"(i) any food additive that is unsafe within
6	the meaning of section 409, or
7	''(ii) a new animal drug (or conversion
8	product thereof) that is unsafe within the
9	meaning of section 512; or".
10	SEC. 305. TOLERANCES AND EXEMPTIONS FOR PESTICIDE
11	CHEMICAL RESIDUES.
12	Section 408 (21 U.S.C. 346a) is amended to read as
13	follows:
14	"TOLERANCES AND EXEMPTIONS FOR PESTICIDE
15	CHEMICAL RESIDUES
16	"Sec. 408. (a) Requirement for Tolerance or
17	Exemption.—
18	"(1) GENERAL RULE.—For the purposes of this
19	section, the term 'food,' when used as a noun with-
20	out modification, shall mean a raw agricultural com-
21	modity or processed food. Except as provided in
22	paragraph (2) or (3), any pesticide chemical residue
23	in or on a food shall be deemed unsafe for the pur-
24	pose of section 402(a)(2)(B) unless—
25	"(A) a tolerance for such pesticide chemi-
26	cal residue in or on such food is in effect under

1	this section and the concentration of the residue
2	is within the limits of the tolerance, or
3	"(B) an exemption from the requirement
4	of a tolerance is in effect under this section for
5	the pesticide chemical residue.
6	"(2) Processed Food.—Notwithstanding
7	paragraph (1)—
8	"(A) if a tolerance is in effect under this
9	section for a pesticide chemical residue in or on
10	a raw agricultural commodity, a pesticide chem-
11	ical residue that is present in or on a processed
12	food because the food is made from that raw
13	agricultural commodity shall not be considered
14	unsafe within the meaning of section
15	402(a)(2)(B) despite the lack of a tolerance for
16	the pesticide chemical residue in or on the proc-
17	essed food if the concentration of the pesticide
18	chemical residue in the processed food when
19	ready for consumption or use is not greater
20	than the tolerance prescribed for the pesticide
21	chemical residue in the raw agricultural com-
22	modity.
23	"(B) If an exemption from the requirement
24	for a tolerance is in effect under this section for
25	a pesticide chemical residue in or on a raw agri-

1	cultural commodity, a pesticide chemical residue
2	that is present in or on a processed food be-
3	cause the food is made from that raw agricul-
4	tural commodity shall not be considered unsafe
5	within the meaning of section $402(a)(2)(B)$ .
6	"(3) Residues of Degradation Products.—
7	If a pesticide chemical residue is present in or on a
8	food because it is a metabolite or other degradation
9	product of a precursor substance that itself is a pes-
10	ticide chemical or pesticide chemical residue, such a
11	residue shall not be considered to be unsafe within
12	the meaning of section 402(a)(2)(B) despite the lack
13	of a tolerance or exemption from the need for a tol-
14	erance for such residue in or on such food if—
15	"(A) the Administrator has not determined
16	that the degradation product is likely to pose
17	any potential health risk from dietary exposure
18	that is of a different type than, or of a greater
19	significance than, any risk posed by dietary ex-
20	posure to the precursor substance, and
21	"(B) either—
22	"(i) a tolerance is in effect under this
23	section for residues of the precursor sub-
24	stance in or on the food, and the combined

level of residues of the degradation product

and the precursor substance in or on the 1 2 food is at or below the stoichiometrically equivalent level that would be permitted by 3 the tolerance if the residue consisted only of the precursor substance rather than the degradation product, or 6 "(ii) an exemption from the need for 7 a tolerance is in effect under this section 8 for residues of the precursor substance in 9 or on the food, and 10 "(C) the tolerance or exemption for resi-11 dues of the precursor substance does not state 12 that it applies only to particular named sub-13 stances or states that it does not apply to resi-14 dues of the degradation product. 15 16 EFFECT OF TOLERANCE OR EXEMP-17 TION.—While a tolerance or exemption from the re-18 quirement for a tolerance is in effect under this sec-19 tion for a pesticide chemical residue with respect to any food, the food shall not by reason of bearing or 20 containing any amount of such a residue be consid-21 22 ered to be adulterated within the meaning of section 23 402(a)(1).

24 "(b) Authority and Standard for Toler-25 ances.—

1	"(1) AUTHORITY.—The Administrator may
2	issue regulations establishing, modifying, or revoking
3	a tolerance for a pesticide chemical residue in or on
4	a food—
5	"(A) in response to a petition filed under
6	subsection (d), or
7	"(B) on the Administrator's initiative
8	under subsection (e).
9	"(2) Standard.—(A) A tolerance may not be
10	established for a pesticide chemical residue in or on
11	a food at a level that is higher than a level that the
12	Administrator determines is adequate to protect the
13	public health.
14	"(B) The Administrator shall modify or revoke
15	a tolerance if it is at a level higher than the level
16	that the Administrator determines is adequate to
17	protect the public health.
18	"(C) In making a determination under this
19	paragraph the Administrator shall take into account,
20	among other relevant factors, the validity, complete-
21	ness, and reliability of the available data from stud-
22	ies of the pesticide chemical residue, the nature of
23	any toxic effects shown to be caused by the pesticide

chemical in such studies, available information and

reasonable assumptions concerning the relationship

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of the results of such studies to human risk, available information and reasonable assumptions concerning the dietary exposure levels of food consumers (and major identifiable subgroups of food consumers) to the pesticide chemical residue, and available information and reasonable assumptions concerning the variability of the sensitivities of major identifiable groups and shall consider other factors to the extent required by subparagraph (F).

"(D) For purposes of subparagraph (A), a tolerance level for a pesticide chemical residue in or on a food shall be deemed to be adequate to protect the public health if the dietary risk posed to food consumers by such level of the pesticide chemical residue is negligible. The Administrator shall by regulation set forth the factors and methods for determining whether such a risk is negligible.

"(E) Where reliable data are available, the Administrator shall calculate the dietary risk posed to food consumers by a pesticide chemical on the basis of the percent of food actually treated with the pesticide chemical and the actual residue levels of the pesticide chemical that occur in food. In particular, the Administrator shall take into account aggregate

pesticide use and residue data collected by the Department of Agriculture.

"(F) For purposes of subparagraph (A), a level of a pesticide chemical residue in or on a food that poses a greater than negligible dietary risk to consumers of the food shall be deemed to be adequate to protect the public health if the Administrator determines that such risk is not unreasonable because—

"(i) use of the pesticide that produces the residue protects humans or the environment from adverse effects on public health or welfare that would, directly or indirectly, result in greater risk to the public or the environment than the dietary risk from the pesticide chemical residue; or

"(ii) use of the pesticide avoids risks to workers, the public, or the environment that would be expected to result from the use of another pesticide or pest control method on the same food and that are greater than the risks that result from dietary exposure to the pesticide chemical residue; or

"(iii) the unavailability of the pesticide would limit the availability to consumers of an

adequate, wholesome, and economical food supply, taking into account regional and domestic effects, and such adverse effects are likely to outweigh the risk posed by the pesticide residue.

In making the determination under this subparagraph, the Administrator shall not consider the effects on any pesticide registrant, manufacturer, or marketer of a pesticide.

- "(3) LIMITATIONS.—(A) A tolerance may be issued under the authority of paragraph (2)(E) only if the Administrator has assessed the extent to which efforts are being made to develop either an alternative method of pest control or an alternative pesticide chemical for use on such commodity or food that would meet the requirements of paragraph (2)(D).
- "(B) A tolerance for a pesticide chemical residue in or on a food shall not be established by the Administrator unless the Administrator determines, after consultation with the Secretary, that there is a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food.

"(C) A tolerance for a pesticide chemical residue in or on a food shall not be established at a level lower than the limit of detection of the method for detecting and measuring the pesticide chemical residue specified by the Administrator under subparagraph (B).

- "(4) International standards.—In establishing a tolerance for a pesticide chemical residue in or on a food, the Administrator shall take into account any maximum residue level for the chemical in or on the food that has been established by the Codex Alimentarius Commission. The Administrator shall determine whether the Codex maximum residue level is adequate to protect the health of United States' consumers and whether the data supporting the maximum residue level are valid, complete, and reliable. If the Administrator determines not to adopt a Codex maximum residue level, the Administrator shall publish a notice in the Federal Register setting forth the reasons.
- 21 "(c) Authority and Standard for Exemp-22 tions.—
- issue a regulation establishing, modifying, or revoking an exemption from the requirement for a toler-

1	ance for a pesticide chemical residue in or on a
2	food—
3	"(A) in response to a petition filed under
4	subsection (d), or
5	"(B) on the Administrator's initiative
6	under subsection (e).
7	"(2) Standard.—(A) An exemption from the
8	requirement for a tolerance for a pesticide chemical
9	residue in or on a food may be established only if
10	the Administrator determines that a tolerance is not
11	needed to protect the public health, in view of the
12	levels of dietary exposure to the pesticide chemical
13	residue that could reasonably be expected to occur
14	"(B) An exemption from the requirement for a
15	tolerance for a pesticide chemical residue in or on a
16	food shall be revoked if the Administrator, in re-
17	sponse to a petition for the revocation of the exemp-
18	tion or at the Administrator's own initiative deter-
19	mines that the exemption does not satisfy the cri-
20	terion of subparagraph (A).
21	"(C) In making a determination under this sub-
22	paragraph, the Administrator shall take into ac-
23	count, among other relevant factors, the factors set
24	forth in subsection (b)(2)(C).

1	"(3) Limitation.—An exemption from the re-
2	quirement for a tolerance for a pesticide chemical
3	residue in or on a food shall not be established by
4	the Administrator unless the Administrator deter-
5	mines, after consultation with the Secretary—
6	"(A) that there is a practical method for
7	detecting and measuring the levels of such pes-
8	ticide chemical residue in or on such food; or
9	"(B) that there is no need for such a
10	method, and states the reasons for such deter-
11	mination in the order issuing the regulation es-
12	tablishing or modifying the regulation.
13	"(d) Petition for Tolerance or Exemption.—
14	"(1) Petitions and Petitioners.—Any per-
15	son may file with the Administrator a petition pro-
16	posing the issuance of a regulation—
17	"(A) establishing, modifying, or revoking a
18	tolerance for a pesticide chemical residue in or
19	on a food, or
20	"(B) establishing or revoking an exemption
21	from the requirement of a tolerance for such a
22	residue.
23	"(2) Petition contents.—
24	"(A) Establishment.—A petition under
25	paragraph (1) to establish a tolerance or ex-

1	emption for a pesticide chemical residue shall
2	be supported by such data and information as
3	are specified in regulations issued by the Ad-
4	ministrator, including—
5	"(i)(I) an informative summary of the
6	petition and of the data, information, and
7	arguments submitted or cited in support of
8	the petition,
9	"(II) a statement that the petitioner
10	agrees that such summary or any informa-
11	tion it contains may be published as a part
12	of the notice of filing of the petition to be
13	published under this subsection and as
14	part of a proposed or final regulation is-
15	sued under this section,
16	"(ii) the name, chemical identity, and
17	composition of the pesticide chemical resi-
18	due and of the pesticide chemical that pro-
19	duces the residue,
20	''(iii) data showing the recommended
21	amount, frequency, method, and time of
22	application of that pesticide chemical,
23	"(iv) full reports of tests and inves-
24	tigations made with respect to the safety of
25	the pesticide chemical, including full infor-

1	mation as to the methods and controls
2	used in conducting those tests and inves-
3	tigations,
4	"(v) full reports of tests and inves-
5	tigations made with respect to the nature
6	and amount of the pesticide chemical resi-
7	due that is likely to remain in or on the
8	food, including a description of the analyt-
9	ical methods used,
10	"(vi) a practical method for detecting
11	and measuring the levels of the pesticide
12	chemical residue in or on the food, or a
13	statement why such a method is not need-
14	ed,
15	"(vii) practical methods for removing
16	any amount of the residue that would ex-
17	ceed any proposed tolerance,
18	"(viii) a proposed tolerance for the
19	pesticide chemical residue, if a tolerance is
20	proposed,
21	"(ix) all relevant data bearing on the
22	physical or other technical effect that the
23	pesticide chemical is intended to have and
24	the quantity of the pesticide chemical that
25	is required to produce the effect.

1	"(x) if the petition relates to a toler-
2	ance for a processed food, reports of inves-
3	tigations conducted using the processing
4	method(s) used to produce that food,
5	"(xi) such information as the Admin-
6	istrator may require to make the deter-
7	mination under subsection (b)(2)(E), and
8	"(xii) such other data and information
9	as the Administrator requires by regulation
10	to support the petition.
11	If information or data required by this subpara-
12	graph is available to the Administrator, the per-
13	son submitting the petition may cite the avail-
14	ability of the information or data in lieu of sub-
15	mitting it. The Administrator may require a pe-
16	tition to be accompanied by samples of the pes-
17	ticide chemical with respect to which the peti-
18	tion is filed.
19	"(B) Modification or revocation.—
20	The Administrator may by regulation establish
21	the requirements for information and data to
22	support a petition to modify or revoke a toler-
23	ance or to revoke an exemption from the re-
24	quirement for a tolerance.

tion that the Administrator determines has met the requirements of paragraph (2) shall be published by the Administrator within 30 days after such determination. The notice shall announce the availability of a description of the analytical methods available to the Administrator for the detection and measurement of the pesticide chemical residue with respect to which the petition is filed or shall set forth the petitioner's statement of why such a method is not needed. The notice shall include the summary required by paragraph (2)(A)(i).

- "(4) ACTIONS BY THE ADMINISTRATOR.—The Administrator shall, after giving due consideration to a petition filed under paragraph (1) and any other information available to the Administrator—
  - "(A) issue a final regulation (which may vary from that sought by the petition) establishing, modifying, or revoking a tolerance for the pesticide chemical residue or an exemption of the pesticide chemical residue from the requirement of a tolerance;
- "(B) issue a proposed regulation under subsection (e), and thereafter either issue a

final regulation under subsection (e) or an order denying the petition; or 

"(C) issue an order denying the petition.

"(5) EFFECTIVE DATE.—A regulation issued under paragraph (4) shall take effect upon publication.

## "(6) Further proceedings.—

"(A) Within 60 days after a regulation or order is issued under paragraph (4), subsection (e)(1), or subsection (f)(1), any person may file objections thereto with the Administrator, specifying with particularity the provisions of the regulation or order deemed objectionable and stating reasonable grounds therefor. If the regulation or order was issued in response to a petition under paragraph (d)(1), a copy of each objection filed by a person other than the petitioner shall be served by the Administrator on the petitioner.

"(B) An objection may include a request for a public evidentiary hearing upon the objection. The Administrator shall, upon the initiative of the Administrator or upon the request of an interested person and after due notice, hold a public evidentiary hearing if and to the extent

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the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections. The presiding officer in such a hearing may authorize a party to obtain discovery from other persons and may upon a showing of good cause made by a party issue a subpoena to compel testimony or production of documents from any person. The presiding officer shall be governed by the Federal Rules of Civil Procedure in making any order for the protection of the witness or the content of documents produced and shall order the payment of reasonable fees and expenses as a condition to requiring testimony of the witness. On contest, such a subpoena may be enforced by a Federal district court.

"(C) As soon as practicable after receiving the arguments of the parties, the Administrator shall issue an order stating the action taken upon each such objection and setting forth any revision to the regulation or prior order that the Administrator has found to be warranted. If a hearing was held under subparagraph (B), such order and any revision to the regulation or prior

order shall, with respect to questions of fact at issue in the hearing, be based only on substantial evidence of record at such hearing, and shall set forth in detail the findings of facts and the conclusions of law or policy upon which the order or regulation is based.

"(D) An order issued under this paragraph ruling on an objection shall not take effect before the 90th day after its publication unless the Administrator finds that emergency conditions exist necessitating an earlier effective date, in which event the Administrator shall specify in the order the Administrator's findings as to such conditions.

"(7) Judicial review.—(A) In a case of actual controversy as to the validity of any order issued under paragraph (6) or any regulation that is the subject of such an order, any person who will be adversely affected by such order or regulation may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein that person resides or has its principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within 60 days after publication

of such order, a petition praying that the order or regulation be set aside in whole or in part.

"(B) A copy of the petition shall be forthwith transmitted by the clerk of the court to the Administrator, or any officer designated by the Administrator for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which the Administrator based the order or regulation, as provided in section 2112 of title 28, United States Code. Upon the filing of such a petition, the court shall have exclusive jurisdiction to affirm or set aside the order or regulation complained of in whole or in part. The findings of the Administrator with respect to questions of fact shall be sustained only if supported by substantial evidence when considered on the record as a whole.

"(C) If a party applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that the additional evidence is material and that there were reasonable grounds for the failure to adduce the evidence in the proceeding before the Administrator, the court may order that the additional evidence (and evidence in rebuttal thereof) shall be taken before the Administrator in the manner and upon the terms and conditions the

- court deems proper. The Administrator may modify prior findings as to the facts by reason of the additional evidence so taken and may modify the order or regulation accordingly. The Administrator shall file with the court any such modified finding, order, or regulation.
  - "(D) The judgment of the court affirming or setting aside, in whole or in part, any order under paragraph (6) and any regulation which is the subject of such an order shall be final, subject to review by the Supreme Court of the United States as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this paragraph shall not, unless specifically ordered by the court to the contrary, operate as a stay of a regulation or order.
    - "(E) Any issue as to which review is or was obtainable under paragraph (6) and this paragraph shall not be the subject of judicial review under any other provision of law.
- 21 "(e) Action on Administrator's Own Initia-
- 22 TIVE.—

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- 23 "(1) GENERAL RULE.—The Administrator may
- 24 issue a regulation—

1	"(A) establishing, modifying, or revoking a
2	tolerance for a pesticide chemical or a pesticide
3	chemical residue,
4	"(B) establishing or revoking an exemption
5	of a pesticide chemical residue from the require-
6	ment of a tolerance, or
7	"(C) establishing general procedures and
8	requirements to implement this section.
9	A regulation issued under this paragraph shall be-
10	come effective upon its publication.
11	"(2) NOTICE.—Before issuing a final regulation
12	under paragraph (1), the Administrator shall issue
13	a notice of proposed rulemaking and provide a pe-
14	riod of not less than 60 days for public comment on
15	the proposed regulation, except that a shorter period
16	for comment may be provided if the Administrator
17	for good cause finds that it would be contrary to the
18	public interest to do so and states the reasons for
19	the finding in the notice of proposed rulemaking.
20	The Administrator shall provide an opportunity for
21	a public hearing during the rulemaking under proce-
22	dures provided in subsection $(d)(6)(B)$ .
23	"(f) Special Data Requirements.—
24	"(1) Requiring submission of additional
25	DATA.—If the Administrator determines that addi-

1	tional data or information are reasonably required to
2	support the continuation of a tolerance or exemption
3	that is in effect under this section for a pesticide
4	chemical residue on a food, the Administrator
5	shall—
6	"(A) issue a notice requiring the persons
7	holding the pesticide registrations associated
8	with such tolerance or exemption to submit the
9	data or information under section 3(c)(2)(B) of
10	the Federal Insecticide, Fungicide, and
11	Rodenticide Act,
12	"(B) issue a rule requiring that testing be
13	conducted on a substance or mixture under sec-
14	tion 4 of the Toxic Substances Control Act, or
15	"(C) publish in the Federal Register, after
16	first providing notice and an opportunity for
17	comment of not less than 90 days' duration, an
18	order—
19	''(i) requiring the submission to the
20	Administrator by one or more interested
21	persons of a notice identifying the person
22	or persons who will submit the required
23	data and information,
24	"(ii) describing the type of data and
25	information required to be submitted to

1	the Administrator and stating why the
2	data and information could not be obtained
3	under the authority of section $3(c)(2)(B)$
4	of the Federal Insecticide, Fungicide, and
5	Rodenticide Act or section 4 of the Toxic
6	Substances Control Act,
7	"(iii) describing the reports to the Ad-
8	ministrator required to be prepared during
9	and after the collection of the data and in-
10	formation,
11	"(iv) requiring the submission to the
12	Administrator of the data, information,
13	and reports referred to in clauses (ii) and
14	(iii), and
15	"(v) establishing dates by which the
16	submissions described in clauses (i) and
17	(iv) must be made.
18	The Administrator may revise any such order to cor-
19	rect an error.
20	"(2) Noncompliance.—If a submission re-
21	quired by a notice issued in accordance with para-
22	graph (1)(A) or an order issued under paragraph
23	(1)(B) is not made by the time specified in such no-
24	tice or order, the Administrator may by order pub-

- lished in the Federal Register modify or revoke the tolerance or exemption in question.
  - "(3) REVIEW.—An order issued under this subsection shall be effective upon publication and shall be subject to review in accordance with paragraphs (6) and (7) of subsection (d).
  - "(g) Confidentiality and Use of Data.—
    - "(1) GENERAL RULE.—Data and information that are submitted to the Administrator under this section in support of a tolerance shall be entitled to confidential treatment for reasons of business confidentiality and to exclusive use and data compensation, to the same extent provided by sections 3 and 10 of the Federal Insecticide, Fungicide and Rodenticide Act.
    - "(2) EXCEPTIONS.—Data that are entitled to confidential treatment under paragraph (1) may nonetheless be disclosed to the Congress of the United States, and may be disclosed, under such security requirements as the Administrator may provide by regulation, to—
    - "(A) employees of the United States authorized by the Administrator to examine such data in the carrying out of their official duties

under this Act or other Federal statutes intended to protect the public health, or

- "(B) contractors with the United States authorized by the Administrator to examine such data in the carrying out of contracts under such statutes.
- "(3) SUMMARIES.—Notwithstanding any provision of this subsection or other law, the Administrator may publish the informative summary required by subsection (d)(2)(A)(i) and may, in issuing a proposed or final regulation or order under this section, publish an informative summary of the data relating to the regulation or order.
- 14 "(h) Status of Previously Issued Regula-15 tions.—
  - "(1) REGULATIONS UNDER SECTION 406.—Regulations affecting pesticide chemical residues in or on raw agricultural commodities promulgated, in accordance with section 701(e), under the authority of section 406(a) upon the basis of public hearings instituted before January 1, 1953, shall be deemed to be regulations issued under this section and shall be subject to modification or revocation under subsections (d) and (e).

"(2) REGULATIONS UNDER SECTION 409.—Reg-1 2 ulations that established tolerances for substances that are pesticide chemical residues on or in proc-3 essed food, or that otherwise stated the conditions under which such pesticide chemicals could be safely 5 6 used, and that were issued under section 409 on or 7 before the date of the enactment of this paragraph, shall be deemed to be regulations issued under this 8 section and shall be subject to modification or rev-9 10 ocation under subsection (d) or (e).

- "(3) REGULATIONS UNDER SECTION 408.—Regulations that established tolerances or exemptions under this section that were issued on or before the date of the enactment of this paragraph shall remain in effect unless modified or revoked under subsection (d) or (e).
- 17 "(i) TRANSITIONAL PROVISION.—If, on the day before the date of the enactment of this subsection, a substance that is a pesticide chemical was, with respect to 19 a particular pesticidal use of the substance and any result-20 ing pesticide chemical residue in or on a particular food— 21
- 22 "(1) regarded by the Administrator or the Secretary as generally recognized as safe for use within 23 the meaning of the provisions of section 408(a) or 24 201(s) as then in effect, or

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- 1 "(2) regarded by the Secretary as a substance 2 described by section 201(s)(4),
- 3 such a pesticide chemical residue shall be regarded as ex-
- 4 empt from the requirement for a tolerance, as of the date
- 5 of enactment of this subsection. The Administrator shall
- 6 by regulation indicate which substances are described by
- 7 this subsection. An exemption under this subsection may
- 8 be revoked or modified as if it had been issued under sub-
- 9 section (c).
- 10 "(j) Harmonization With Action Under Other
- 11 Laws.—
- 12 "(1) LIMITATION.—Notwithstanding any other 13 provision of this Act, a final rule under this section 14 that revokes, modifies, or suspends a tolerance or 15 exemption for a pesticide chemical residue in or on 16 a food may be issued only if the Administrator has 17 first taken any necessary action under the Federal
- Insecticide, Fungicide, and Rodenticide Act with re-
- spect to the registration of the pesticide(s) whose
- use results in such residue to ensure that any au-
- thorized use of the pesticide in producing, storing,
- processing, or transporting food that occurs after
- the issuance of such final rule under this section will
- not result in pesticide chemical residues on such

food that are unsafe within the meaning of subsection (a).

> "(2) REVOCATION OF TOLERANCE OR EXEMP-TION FOLLOWING CANCELLATION OF ASSOCIATED REGISTRATIONS.—If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act, cancels the registration of each pesticide that contains a particular pesticide chemical and that is labeled for use on a particular food, or requires that the registration of each such pesticide be modified to prohibit its use in connection with the production, storage, or transportation of such food, due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the Administrator shall revoke any tolerance or exemption that allows the presence of the pesticide chemical, or any pesticide chemical residue that results from its use, in or on that food. The Administrator shall use the procedures set forth in subsection (e) in taking action under this paragraph. A revocation under this paragraph shall become effective not later than 180 days after—

"(A) the date by which each such cancellation of a registration has become effective, or

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	6.6	(B) the da	ate on whi	ch the use	of the	can-
2	celed	pesticide	becomes	unlawful	under	the
3	terms	of the can	cellation,	whichever	is later.	

"(3) Suspension of Tolerance or Exemption following suspension of Associated Registrations.—

"(A) SUSPENSION.—If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act, suspends the use of each registered pesticide that contains a particular pesticide chemical and that is labeled for use on a particular food, due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the Administrator shall suspend any tolerance or exemption that allows the presence of the pesticide chemical, or any pesticide chemical residue that results from its use, in or on that food. The Administrator shall use the procedures set forth in subsection (e) in taking action under this paragraph. A suspension under this paragraph shall become effective not later than 60 days after the date by which each such suspension of use has become effective.

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"(B) EFFECT OF SUSPENSION.—The suspension of a tolerance or exemption under subparagraph (A) shall be effective as long as the use of each associated registration of a pesticide is suspended under the Federal Insecticide, Fungicide, and Rodenticide Act. While a suspension of a tolerance or exemption is effective the tolerance or exemption shall not be considered to be in effect. If the suspension of use of the pesticide under that Act is terminated, leaving the registration of the pesticide for such use in effect under that Act, the Administrator shall rescind any associated suspension of a tolerance or exemption.

"(4) Tolerances for unavoidable residues.—In connection with action taken under paragraph (2) or (3), or with respect to pesticides whose registrations were canceled prior to the effective date of this paragraph, if the Administrator determines that a residue of the canceled or suspended pesticide chemical will unavoidably persist in the environment and thereby be present in or on a food, the Administrator may establish a tolerance for the pesticide chemical residue at a level that permits such unavoidable residue to remain in such food. In estab-

lishing such a tolerance, the Administrator shall take into account the factors set forth in subsection (b)(2)(A)(iii) and shall use the procedures set forth in subsection (e). The Administrator shall review any such tolerance periodically and modify it as necessary so that it allows only that level of the pesticide chemical residue that is unavoidable.

"(5) PESTICIDE RESIDUES RESULTING FROM LAWFUL APPLICATION OF PESTICIDE.—Notwithstanding any other provision of this Act, if a tolerance or exemption for a pesticide chemical residue in or on a food has been revoked, suspended, or modified under this section, an article of that food shall not be deemed unsafe solely because of the presence of such pesticide chemical residue in or on such food if it is shown to the satisfaction of the Secretary that—

"(A) the residue is present as the result of an application or use of a pesticide at a time and in a manner that was lawful under the Federal Insecticide, Fungicide, and Rodenticide Act; and

"(B) the residue does not exceed a level that was authorized at the time of that application or use to be present on the food under a

1	tolerance, exemption, food additive regulation,
2	or other sanction then in effect under this Act
3	unless, in the case of any tolerance or exemption re-
4	voked, suspended, or modified under this subsection
5	or subsection (d) or (e), the Administrator has is-
6	sued a determination that consumption of the legally
7	treated food during the period of its likely availabil-
8	ity in commerce will pose an unreasonable dietary
9	risk.
10	"(k) FEES.—The Administrator shall by regulation
11	require the payment of such fees as will in the aggregate
12	in the judgment of the Administrator, be sufficient over
13	a reasonable term to provide, equip, and maintain an ade-
14	quate service for the performance of the Administrator's
15	functions under this section. Under the regulations, the
16	performance of the Administrator's services or other func-
17	tions under this section, including—
18	"(1) the acceptance for filing of a petition sub-
19	mitted under subsection (d),
20	"(2) the promulgation of a regulation establish-
21	ing, modifying, or revoking a tolerance or establish-
22	ing or revoking an exemption from the requirement
23	of a tolerance under this section,
24	"(3) the acceptance for filing of objections
25	under subsection (d)(6), or

"(4) the certification and filing in court of a 1 2 transcript of the proceedings and the record under subsection (d)(7), 3 4 may be conditioned upon the payment of such fees. The regulations may further provide for waiver or refund of fees in whole or in part when in the judgment of the Administrator such a waiver or refund is equitable and not contrary to the purposes of this subsection. 8 9 "(I) NATIONAL UNIFORMITY OF TOLERANCES.— 10 "(1) Qualifying pesticide chemical resi-11 DUE.—For purposes of this subsection, the term 'qualifying pesticide chemical residue' means a pes-12 ticide chemical residue resulting from the use, in 13 14 production, processing, or storage of a food, of a pesticide chemical that is an active ingredient and 15 that— 16 17 "(A) was first approved for such use in a 18 registration of a pesticide issued under section 19 3(c)(5) of the Federal Insecticide, Fungicide, 20 Rodenticide Act on or after April 25, 1985, on the basis of data determined by the Adminis-21 22 trator to meet all applicable requirements for data prescribed by regulations in effect under 23

that Act on April 25, 1985; or

1	"(B) was approved for such use in a rereg-
2	istration eligibility determination issued under
3	section 4(g) of that Act on or after the date of
4	enactment of the Food Quality Protection Act
5	of 1993.
6	"(2) Qualifying federal determination.—
7	For purposes of this subsection, the term 'qualifying
8	Federal determination' means—
9	"(A) a tolerance or exemption from the re-
10	quirement for a tolerance for a qualifying pes-
11	ticide chemical residue that was—
12	"(i) issued under this section after the
13	date of enactment of the Food Quality
14	Protection Act of 1993;
15	"(ii) issued (or, pursuant to sub-
16	section (h) or (i), deemed to have been is-
17	sued) under this section, and determined
18	by the Administrator to meet the standard
19	under subsection (b)(2) (in the case of a
20	tolerance) or (c)(2) (in the case of an ex-
21	emption); and
22	"(B) any statement, issued by the Sec-
23	retary, of the residue level below which enforce-
24	ment action will not be taken under this Act
25	with respect to any qualifying pesticide chemi-

cal residue, if the Secretary finds that such pesticide chemical residue level permitted by such statement during the period to which such statement applies protects human health.

"(3) LIMITATION.—The Administrator may make the determination described in paragraph (2)(A)(ii) only by issuing a rule in accordance with the procedure set forth in subsection (d) or (e) and only if the Administrator issues a proposed rule and allows a period of not less than 30 days for comment on the proposed rule. Any such rule shall be reviewable in accordance with subsections (d)(6) and (d)(7).

"(4) STATE AUTHORITY.—Except as provided in paragraph (5), no State or political subdivision may establish or enforce any regulatory limit on a qualifying pesticide chemical residue in or on any food if a qualifying Federal determination applies to the presence of such pesticide chemical residue in or on such food, unless such State regulatory limit is identical to such qualifying Federal determination. A State or political subdivision shall be deemed to establish or enforce a regulatory limit on a pesticide chemical residue in or on food if it purports to prohibit or penalize the production, processing, ship-

ping, or other handling of a food because it contains a pesticide residue (in excess of a prescribed limit), or if it purports to require that a food containing a pesticide residue be the subject of a warning or other statement relating to the presence of the pesticide residue in the food.

## "(5) PETITION PROCEDURE.—

"(A) Any State may petition the Administrator for authorization to establish in such State a regulatory limit on a qualifying pesticide chemical residue in or on any food that is not identical to the qualifying Federal determination applicable to such qualifying pesticide chemical residue.

"(B) Any petition under subparagraph (A) shall—

"(i) satisfy any requirements prescribed, by rule, by the Administrator; and

"(ii) be supported by scientific data about the pesticide chemical residue that is the subject of the petition or about chemically related pesticide chemical residues, data on the consumption within such State of food bearing the pesticide chemical residue, and data on exposure of humans with-

1	in such State to the pesticide chemical res-
2	idue.
3	"(C) Subject to paragraph (6), the Admin-
4	istrator may, by order, grant the authorization
5	described in subparagraph (A) if the Adminis-
6	trator determines that the proposed State regu-
7	latory limit—
8	''(i) is justified by compelling local
9	conditions;
10	"(ii) would not unduly burden inter-
11	state commerce; and
12	"(iii) would not cause any food to be
13	in violation of Federal law.
14	"(D) In lieu of any action authorized
15	under subparagraph (C), the Administrator
16	may treat a petition under this paragraph as a
17	petition under subsection (d) to revoke or mod-
18	ify a tolerance or to revoke an exemption. If the
19	Administrator determines to treat a petition
20	under this paragraph as a petition under sub-
21	section (d), the Administrator shall thereafter
22	act on the petition pursuant to subsection (d).
23	"(E) Any order of the Administrator
24	granting or denying the authorization described
25	in subparagraph (A) shall be subject to review

- in the manner described in subsections (d)(6) and (d)(7).
- 3 "(6) Residues from Lawful application.—

No State or political subdivision may enforce any regulatory limit on the level of a pesticide chemical 5 6 residue that may appear in or on any food if, at the 7 time of the application of the pesticide that resulted in such residue, the sale of such food with such resi-8 due level was lawful under this Act and under the 9 10 law of such State, unless the State demonstrates 11 that consumption of the food containing such pes-12 ticide residue level during the period of the food's likely availability in the State will pose an unreason-13 14 able dietary risk to the health of persons within such

## 16 SEC. 306. AUTHORIZATION FOR INCREASE MONITORING.

There is authorized to be appropriated an additional \$12,000,000 for increased monitoring by the Secretary of Health and Human Services of pesticide residues in imported and domestic food.

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State.".

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